REMARKS

In the Office Action dated October 6, 2004, the Examiner has set forth a requirement for restriction under 35 U.S.C. §121, alleging that the subject matter defined by the claims of the present invention represents the following two separate and distinct inventions:

I. Claims 8-18, drawn to a method of assaying the reactivity of a subject to IDDM autoantigen, classified in Class 424, subclass 278.1.

II. Claims 19-29 and 37-40, drawn to peptide, classified in Class 530, subclass 350.

The Examiner further requires that, whichever Group is elected, Applicants further elect a specific peptide, such as one of those listed in Claim 14 or 15.

In support of the present restriction requirement, the Examiner has alleged that the subject matter defined by the claims of the present invention represents two separate and distinct groups. The Examiner acknowledges that Groups II and I are related as products and process of use. However, the Examiner alleges that Groups II and I are patentably distinct because the claimed products can be used in a materially different process such as to generate antibodies.

In order to be fully responsive to the Examiner's requirement for restriction, Applicants provisionally elect, with traverse, the subject matter of Group I, claims 8-18, drawn to a method of assaying the reactivity of a subject to IDDM autoantigen. Applicants further provisionally elect, with traverse, a specific peptide recited in Claim 14, wherein X_2 is set forth in SEQ ID NO: 1, for continued prosecution. Applicants reserve the right to file one or more divisional applications directed to the non-elected subject matter in the present application.

However, pursuant to 37 C.F.R. §§1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

An Examiner's authority to require restriction is defined and limited by statute:

> If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.

35 U.S.C. §121, first sentence (emphasis added).

The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent and distinct, 37 C.F.R. §§1.141-142. Without a showing of independence and distinctness, a restriction requirement is unauthorized. In the present application, the claims which the Examiner has grouped separately are not "independent and distinct" so as to justify the restriction requirement.

Applicants respectfully submit that the present invention is directed to composition and methods for the use of certain molecules, such as peptides, which interact immunologically with antibodies or T-cells in subjects having pre-clinical or clinical Insulin-Dependent Diabetes Mellitus (IDDM). Such peptides can be employed as diagnostic, therapeutic and prophylactic agents for IDDM. More specifically, Applicants respectfully submit that Groups II and I are related as a product and process of using the product, as the Examiner has conceded. Applicants further submit that the subject matter of the claims in Groups II and I are not independent and distinct. Specifically, methods as claimed in Group I are all directed to assaying the reactivity of a subject to IDDM autoantigen by employing the molecules or compositions of Group II. Applicants respectfully submit that Group I employs the product/composition and embodies the concept of Group II. Thus, Groups I and II are

interrelated and interdependent. Therefore, Applicants respectfully submit that the subject matter Groups I and II are clearly linked to each other by a single inventive concept – they are merely different aspects of a single invention. Groups I and II are not "independent and distinct".

Applicants also respectfully submit that the present invention employs certain molecules, such as peptides, which interact immunologically with antibodies or T-cells in subjects having pre-clinical or clinical IDDM. Thus, the peptides that interact immunologically with antibodies or T-cells in subjects having pre-clinical or clinical IDDM, such as those recited in Claims 14-15 wherein X_2 is set forth in either SEQ ID NO: 1 or SEQ ID NO: 2, are related to each other as aspects of the single concept of the present invention.

Applicants further submit that the interdependence of Groups I and II is confirmed --indeed, it is mandated-- by virtue of the fact that 35 U.S.C. §112 compels disclosure of all aspects of the invention in the one application which applicants have filed. For example, an application claiming a peptide composition capable of reacting with T-cells and modifying T-cell function when incubated with cells from subjects having pre-clinical or clinical IDDM to assay reactivity of a subject to IDDM autoantigen is required to disclose, *inter alia*, how to make and use that composition. In other words, a description of the means and method for producing and using the subject composition is a mandatory part of the application to the composition, and *vice versa*. Indeed, if any of these aspects of a complete disclosure were omitted, the application could be considered defective under §112, first paragraph. Consequently, it is clear that aspects of a given invention, such as a product, its use, and the process of producing that product, are necessarily interdependent, not independent, from each other.

The Examiner has specifically justified the restriction requirement in this case by reference to the different classes and subclasses of the Patent and Trademark Office classification

system in which the two groups of claims would allegedly be classed. This basis fails to justify the restriction requirement in this application. Applicants respectfully submit that the Examiner by searching the literature of claimed methods of Group I, which employ products of Group II, necessarily would search the literature regarding products of Group II. *Prima facie* then there should be no necessity for non-coextensive literature searches in relation to the subject matter of Groups I and II.

Moreover, reliance on the classification of the groups of claims does not establish independence and distinctness. The classification system has no statutory recognition as evidence of whether inventions are independent and distinct. The classification system is instead an aid in finding and searching for patents.

The classification system is also an unreliable basis for requiring restriction between claims to the various aspects of applicants' unitary invention, because the system exhibits considerable overlap in technical definitions. In particular, the definitions of subclasses in the classification system do not prevent the Examiner from basing patentability decisions, as to claims assigned to one group, on patent references found in the subclass(es) with which the Examiner associated another group of claims.

Furthermore, the classification system is a poor basis for requiring restriction between related aspects of an invention because classifications and definitions change over time. Thus, a classification that might have seemed to support restriction at a given time could change, thereby casting a shadow over the propriety of the restriction requirement later on during the term of the patents issuing from parent and divisional applications. Indeed, classifications seem largely to change in response to considerations of administrative convenience, and often in response to nothing more than growth in the number of patents in a given class or subclass.

These considerations have nothing to do with whether the subject matter of patents assigned to different classifications is "independent and distinct" as those terms are used in 35 U.S.C. §121, which fact proves that basing restriction requirements on the classification system is improper.

Accordingly, Groups I-II are very clearly interrelated and interdependent, not "independent and distinct".

In addition, the courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the Applicants have done herein. The CCPA has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

Applicants respectfully suggest that in view of the continued increase of official fees and the potential limitation of an applicants financial resources, a practice which arbitrarily imposes two-way restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the implementation of the General Agreement on Trade and Tariffs (GATT), Applicants are required either to conduct simultaneous prosecution, as here requiring excessive filing costs, or otherwise compromise the term of their patent assets.

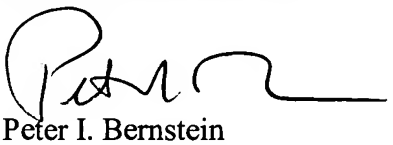
It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that §121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle mbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986); and in Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990) that court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public's interest in the legitimacy of issued patents, Applicants respectfully urge the Examiner not to require restriction in cases such as the present application wherein various aspects in a unitary invention are claimed.

Finally, Applicants respectfully submit that a determination to make the pending restriction requirement final must evidence the patentable distinctness of both defined groups, one from the other, as presented by the Examiner.

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,



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